

05-28-04

*17/11*  
PATENT

Attorney Docket No. 9233-14DV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe

Application Serial No.: 10/808,044

Filed: March 24, 2004

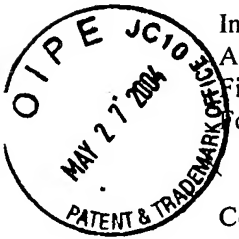
For: *Amphiphilic Prodrugs*

Date: May 27, 2004

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450



**INFORMATION DISCLOSURE STATEMENT CITATION UNDER 37 C.F.R. § 1.97**

Sir:

Attached are ten sheets of form PTO-1449 as submitted in parent application serial no. 09/474,915, filed December 31, 1999, with the parent application serial no., attorney docket no., filing date and art unit crossed out and the current attorney docket no. written in. Also attached is a form PTO-1449, providing a list of documents 1-22. Documents 1-3 have previously made of record in application serial number 09/474,915. Because these references have already been made of record in the parent application, a copy of each of these references is not provided herein. However, applicants will provide a copy of any such reference cited herein upon request from the Examiner. Copies of documents 4-22 are enclosed. Applicants respectfully request that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. §1.97 and Section 609 of the MPEP.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment, to Deposit Account No. 50-0220.

Respectfully submitted,

*Mary L. Miller*

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**CERTIFICATE OF EXPRESS MAILING**

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I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*Cathy A. Schetzina*  
Cathy A. Schetzina

**FORM PTO-1449** U.S. Department of Commerce  
Patent and Trademark Office

Attorney Docket Number  
9233.14DV

Serial No.  
10/808,044

**LIST OF DOCUMENTS CITED BY APPLICANT**

(Use several sheets if necessary)

Applicants: Ekwuribe et al.

Filing Date: March 24, 2004

Group

**U. S. PATENT DOCUMENTS**

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1.	5,681,811	10/28/1997	Ekwuribe			
	2.	6,380,405	04/30/2002	Ekwuribe			
	3.	6,310,039	10/30/2001	Kratz			
	4.	6,713,454	03/30/2004	Ekwuribe			
	5.	6,309,633	10/30/2001	Ekwuribe			
	6.	6,703,381	03/09/2004	Ekwuribe			
	7.	6,541,508	04/01/2003	Ekwuribe			

**FOREIGN PATENT DOCUMENTS**

		Document Number	Date	Country	Class	Subclass	Translation Yes   No
	8.	772074	11/10/2000	AU			
	9.	WO 01/19406	03/22/2001	PCT			
	10.	WO 00/78302	12/28/2000	PCT			
	11.	WO 00/09073	02/24/2000	PCT			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	12.	U.S. Provisional Application No. 60/153,649, entitled "Amphiphilic Prodrugs," filed September 13, 1999.
	13.	U.S. Provisional Application No. 60/153,579, entitled "Taxane Prodrugs," filed September 13, 1999
	14.	U.S. Patent Application No. 10/018,879, entitled "Amphiphilic Insulin-Oligomer Conjugates with Hydrolyzable Lipophile Components," filed August 5, 2002
	15.	International Search Report Corresponding to International Application No. PCT/US 00/24523; Date of Mailing: August 6, 2001

EXAMINER

DATE CONSIDERED

\*EXAMINER

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449	US Dept. of Commerce Patent and Trademark Office	ATTORNEY DOCKET NO. <del>4012-122</del> 9233.142	SERIAL NO. <del>10/808,044</del> 09/474,915
INFORMATION DISCLOSURE STATEMENT  (use several sheets if necessary)		APPLICANT  Nnochiri Ekwuribe et al.	
		FILING DATE March 24, 2004 <del>December 31, 1999</del>	GROUP  Not Yet Assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,407,683	18 Apr. 1995	Shively, Merrick L.	424	439	
	AB	5,422,364	6 Jun. 1995	Nicolaou, et al.	514	449	
	AC	5,439,686	8 Aug. 1995	Desai et al.	424	451	
	AD	5,484,809	16 Jan. 1996	Hostetler et al.	514	449	
	AE	5,560,933	1 Oct 1996	Soon-Shiong et al.	424	489	
	AF	5,608,087	4 Mar. 1997	Nicolaou et al.	549	510	
	AG	5,795,909	18 Aug. 1998	Shashoua et al.	514	449	
	AH	5,817,840	6 Oct. 1998	Nicolaou et al.	549	510	
	AI	5,932,462	2 Aug. 1999	Harris et al.	435	188	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO
	AJ	WO 97/33552	18 Sep. 1997	PCT				
	AK	WO 98/58927	30 Dec. 1998	PCT				

## OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)

	AL	Adams, Jonathan D., et al. "Taxol: A History of Pharmaceutical Development and Current Pharmaceutical Concerns." J. Natl Cancer Inst Monographs (1993) 15: 141-147
	AM	Arbuck, S.G. "Taxol (paclitaxel): Future directions." Annals of Oncology (1994) 5(Suppl 6): S59-S62
	AN	Beijnen, Jos H., et al. "Bioanalysis, Pharmacokinetics, and Pharmacodynamics of the Novel Anticancer Drug Paclitaxel (Taxol)." Sem in Oncology (1994) 21 (5) (Suppl 8 October) 53-62
	AO	Deutsch, H.M., et al. "Synthesis of Congeners and Prodrugs. 3. Water-Soluble Prodrugs of Taxol with Potent Antitumor Activity." J Medicinal Chem (1989) 32: 788-792
	AP	Greenwald, R.B., et al. "Drug Delivery Systems: Water Soluble Taxol 2'-Poly(ethylene) glycol) Ester Prodrugs - Design and <i>in Vivo</i> Effectiveness." J. Medicinal Chem (1996) 39:424-431
	AQ	Greenwald, R.B. et al. "Highly Water Soluble Taxol Derivatives: 7-Polyethylene Glycol Carbamates and Carbonates." J Org Chem (1995) 60: 331-336

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Examiner	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.	

FORM PTO-1449		US Dept. of Commerce Patent and Trademark Office		ATTORNEY DOCKET NO. <del>4012-122</del> 9233.14DV		SERIAL NO. 10/808,044 <del>09/474,915</del>	
INFORMATION DISCLOSURE STATEMENT  (use several sheets if necessary)				APPLICANT Nnochiri Ekwuribe et al.			
				FILING DATE March 24, 2004 <del>December 31, 1999</del>		GROUP Not Yet Assigned	
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES      NO
<b>OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)</b>							
	AR	Horwitz, S.B. "TAXOL (paclitaxel): Mechanisms of action." Annals of Oncology (1994) 5 (Suppl.6): S3-S6.					
	AS	Kingston, David G.I. "Taxol: the chemistry and structure-activity relationships of a novel anticancer agent." TIBTECH (June 1994) 12: 222-227					
	AT	Kingston, David G.I. "The chemistry of Taxol." Pharmac Ther (1991) 52: 1-33					
	AU	Kohler, David R., et al. "Paclitaxel (Taxol)." (1994) Pharmacotherapy 14 (1): 3-34					
	AV	Long, Harry J. " Paclitaxel (Taxol): A Novel Anticancer Chemotherapeutic Drug." Mayo Clin Proc (1994) 69: 341-345					
	AW	Parekh, H. et al. "The Transport and Binding of Taxol." Gen Pharmac (1997) 29 (2): 167-172					
	AX	Preston, N.J. "Paclitaxel (Taxol) - a guide to administration." European J of Cancer Care (1996) 5: 147-152					
	AY	Rowinsky, Eric K. et al. "The Clinical Pharmacology and Use of Antimicrotubule Agents in Cancer Chemotherapeutics." Pharmac Ther (1991) 52: 35-84					
	AZ	Rowinsky, Eric K. et al. "Taxol: The First of the Taxanes, an Important New Class of Antitumor Agents." Seminars in Oncology (1992 Dec) 19(6): 646-662					
	BA	Rowinsky, Eric K. et al. "Taxol: Pharmacology, Metabolism and Clinical Implications." Cancer Surveys (1993) 17: 283-304					
	BB	Straubinger, Robert M. et al. "Novel Taxol Formulations: Taxol-Containing Liposomes." J Nat Cancer Inst Monographs (1993) No.15: 69-78					
	BC	Workman, Paul. "Pharmacokinetics and Cancer: Successes, Failures and Future Prospects." Cancer Surveys (1993) 17: 1-26					
	BD	Delgado et al. "The Uses and Properties of PEG-Linked Proteins". Critical Review in Therapeutic Drug Carrier Systems, 9(3, 4):249-304 (1992).					
Continued on page 3							
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FORM PTO-1449		US Dept. of Commerce Patent and Trademark Office		ATTORNEY DOCKET NO. <del>4012-122</del> 9233.14DV		SERIAL NO. 10/808P44 <del>09/474,915</del>	
INFORMATION DISCLOSURE STATEMENT  (use several sheets if necessary)				APPLICANT  Nnochiri Ekwuribe et al.			
				FILING DATE March 24, 2004 <del>December 31, 1999</del>		GROUP  Not Yet Assigned	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BE	4,636,505	Jan 13, 1987	Howard Tucker	514	256	
	BF	5,618,528	Apr 8, 1997	Cooper et al.	424	78.3	
	BG	5,744,592	Apr 28, 1998	Hostetler et al.	536	22.1	
	BH	5,817,321	Oct 6, 1998	Alakhov et al.	424	400	
	BI	4,567,253	Jan 28, 1986	Durst et al.	536	18.1	
	BJ	5,605,976	Feb 25, 1997	Martinez et al.	525	408	
	BK	5,840,900	Nov 24, 1998	Greenwald et al.	546	48	
	BL	5,880,131	Mar 9, 1999	Greenwald et al.	514	279	
	BM	5,932,462	Aug. 3, 1999	Harris et al.	435	188	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	BN	EP 0 423 747 B1	17.10.1990	Europe	C07H 17	04	X
	BO	WO 98/10651	19 Mar 1998	WIPO	A01N	37/18	X
OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)							
	BP	Doyle et al. "Second generation analogs of etoposide and mitomycin C." <i>Cancer Treatment Reviews</i> (1990) 17, 127-131.					
	BQ	Abstract. Spigelman MK et al. "Effect of intracarotid etoposide on opening the blood-brain barrier." <i>Cancer Drug Deliv</i> 1984 Summer; 1(3):207-11.					
	BR	Etoposide Conjugates Search in Chemical Abstracts File					
	BT	"Indications for Etoposide" <a href="http://www.medscape.com/FirstDataBank/cc...20%20%20%20%20%20%20%20%20%&amp;joc:_seqno=3930">http://www.medscape.com/FirstDataBank/cc...20%20%20%20%20%20%20%20%20%&amp;joc:_seqno=3930</a> ; September 3, 1999					
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Examiner						DATE CONSIDERED	
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FORM PTO-1449		US Dept. of Commerce Patent and Trademark Office		ATTORNEY DOCKET NO. <b>9233.140v</b> <del>4012-122</del>		SERIAL NO. <b>19808,044</b> <del>09/474,915</del>	
INFORMATION DISCLOSURE STATEMENT  (use several sheets if necessary)				APPLICANT  Nnochiri Ekwuribe et al.			
				FILING DATE <b>march 24, 2004</b> <del>December 31, 1999</del>		GROUP  Not Yet Assigned	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES    NO
	BU	WO 94/04484	3 Mar 94	PCT			X
	BV	WO 94/12463	June 94	PCT			X
OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)							
	BW	Simon Joel "Antitumour Treatment; The Clinical Pharmacology of Etoposide: an update". <i>Cancer Treatment Reviews</i> (1996) 22, 179-221.					
	BX	"Epipodophyllotoxins". Chapter 51 Antineoplastic Agents. 1261-1262.					
Continue on page __							
Examiner						DATE CONSIDERED	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.							

A circular ink stamp from the Office of the Patent and Trademark Office. The text "O I P E J C 1 0" is curved along the top inner edge, and "PATENT &amp; TRADEMARK OFFICE" is curved along the bottom inner edge. In the center, the date "MAY 27 2004" is stamped. To the left of the stamp, the words "RE" and "NT" are visible from another stamp.

**Complete if Known**

Application Number	09/474,915 <b>10/208,404</b>
Filing Date	<del>December 31, 1999</del> <b>March 24, 2004</b>
First Named Inventor	Nnochiri N. Ekwuribe
Group Art Unit	<del>1623</del>
Examiner Name	<del>Leigh Maier</del>
Attorney Docket Number	9233.14 <b>PK</b>

Sheet	1	of	1
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## U.S. PATENTS AND PATENT PUBLICATIONS

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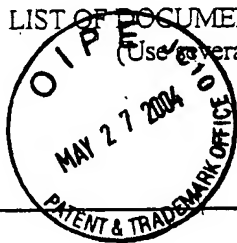
## FOREIGN PATENT DOCUMENTS

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## OTHER NON PATENT LITERATURE DOCUMENTS

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Date Considered

<b>FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office</b>				<b>Attorney Docket Number</b> 9233.140V		<b>Serial No.</b> <del>09/474,915</del> 10/808,044	
<b>LIST OF DOCUMENTS CITED BY APPLICANT</b> (Use several sheets if necessary)				<b>Applicants:</b> Ekwuribe, et al.			
				<b>Filing Date:</b> <del>December 31, 1999</del> March 24, 2004		<b>Group Art Unit:</b> 1623	
<b>U. S. PATENT DOCUMENTS</b>							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number	Date	Country	Class	Subclass	Translation Yes   No
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	1.	Chabner et al., "Antineoplastic Agents: Epipodophyllotoxins," <i>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</i> , Ed. Hardman et al., Ninth Edition, Chapter 51, 1261-1262 (McGraw-Hill, 1996).					

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DATE CONSIDERED \_\_\_\_\_

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<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office				Attorney Docket Number <b>9233.14 DV</b>		Serial No. <del>09/474,913</del> <b>10/808,044</b>	
<b>LIST OF DOCUMENTS CITED BY APPLICANT</b> (Use several sheets if necessary)				Applicants: Ekwuribe, et al.			
				Filing Date: <del>December 31, 1999</del> <b>March 24, 2004</b>		Group Art Unit: <del>1623</del>	

	27.	6,113,906	09/05/00	Greenwald et al.	424	194.1	
	28.	6,127,355	10/03/00	Greenwald et al.	514	183	
	29.	6,153,655	11/28/00	Martinez et al.	514	772.3	
	30.	6,177,087	01/23/01	Greenwald et al.	424	278.1	
	31.	6,180,095	01/30/01	Greenwald et al.	424	85.1	
	32.	6,194,580	02/27/01	Greenwald et al.	546	48	

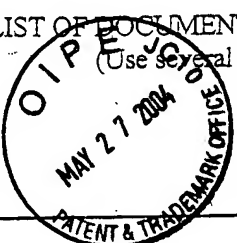
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		

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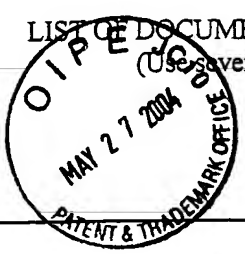
DATE CONSIDERED \_\_\_\_\_

<b>FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office</b>				<b>Attorney Docket Number 9233.14DV</b>		<b>Serial No. <del>09/474,915</del> 10/808,044</b>	
<b>LIST OF DOCUMENTS CITED BY APPLICANT</b> (Use several sheets if necessary)				<b>Applicants: Ekwuribe et al.</b>			
				<b>Filing Date: <del>December 31, 1999</del> March 24, 2004</b>		<b>Group Art Unit: <del>1623</del></b>	
<b>U. S. PATENT DOCUMENTS</b>							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number	Date	Country	Class	Subclass	Translation Yes   No
	1.	WO93/24476	12/09/93	PCT			
	2.	WO94/20453	09/15/94	PCT			
	3.	07082291	03/28/95	JP			X-Abstract
	4.	0 895 784 A1	02/10/99	EP			
	5.	WO99/48536	09/30/99	PCT			
	6.	WO01/13957	03/01/01	PCT			
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							

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<b>U. S. PATENT DOCUMENTS</b>							
Examiner Initial	1.	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	1.	5,122,614	06/16/92	Zalipsky	548	520	
	2.	5,219,564	06/15/93	Zalipsky et al.	424	78.17	
	3.	5,298,643	03/29/94	Greenwald	558	6	
	4.	5,321,095	06/14/94	Greenwald	525	404	
	5.	5,324,844	06/28/94	Zalipsky	548	520	
	6.	5,349,001	09/20/94	Greenwald et al.	525	408	
	7.	5,405,877	04/11/95	Greenwald et al.	514	772.3	
	8.	5,455,027	10/03/95	Zalipsky et al.	424	78.17	
	9.	5,547,981	08/20/96	Greenwald et al.	514	449	
	10.	5,567,422	10/22/96	Greenwald	424	78.3	
	11.	5,612,460	03/18/97	Zalipsky	530	391.9	
	12.	5,614,549	03/25/97	Greenwald et al.	514	449	
	13.	5,622,986	04/22/97	Greenwald et al.	514	449	
	14.	5,637,749	06/10/97	Greenwald	558	6	
	15.	5,643,575	07/01/97	Martinez et al.	424	194.1	
	16.	5,681,567	10/28/97	Martinez et al.	424	178.1	
	17.	5,730,990	03/24/98	Greenwald et al.	424	279.1	
	18.	5,756,593	05/26/98	Martinez et al.	525	403	
	19.	5,808,096	09/15/98	Zalipsky	548	520	
	20.	5,824,701	10/20/98	Greenwald et al.	514	449	
	21.	5,902,588	05/11/99	Greenwald et al.	424	278.1	
	22.	5,919,455	07/06/99	Greenwald et al.	424	178.1	
	23.	5,965,119	10/12/99	Greenwald et al.	424	78.37	
	24.	5,965,566	10/12/99	Greenwald et al.	514	279	
	25.	6,011,042	01/04/00	Greenwald et al.	514	283	
	26.	6,111,107	08/29/00	Greenwald et al.	546	48	

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DATE CONSIDERED \_\_\_\_\_

FORM PTO-1449 U.S. Department of Commerce  
Patent and Trademark OfficeAttorney Docket Number  
9233.14 DVSerial No.  
~~09/474,913~~  
10/808,044LIST OF DOCUMENTS CITED BY APPLICANT  
(Use several sheets if necessary)

Applicants: Ekwuribe, et al.

Filing Date: ~~December 31, 1999~~  
March 24, 2004Group Art  
Unit: 1623

## U. S. PATENT DOCUMENTS

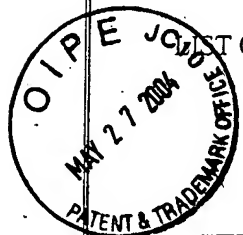
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	1.						
	2.						
	3.						

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes   No
	1.	WO 96/23794	8/8/96	PCT	C07D	491/22	
	2.	WO 97/33552	9/18/97	PCT	A61K	5/00	
	3.	WO 98/07713	2/26/98	PCT	C07D	305/14	
	4..	WO 99/30727	6/24/99	PCT	A61K	38/00	
	5.	WO 00/64486	11/2/00	PCT	A61K	47/48	
	6.	WO 01/19407	3/22/01	PCT	A61K	47/48	

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	1.	Greenwald et al., "Drug Delivery of Anticancer Agents: Water Soluble 4-Poly (Ethylene Glycol) Derivatives of the Lignan, Podophyllotoxin," <i>Journal of Controlled Release</i> , 61:281-294 (1999).
	2.	International Search Report corresponding to International Application No. PCT/US 00/24520; Date of mailing: July 31, 2001.



EXAMINER \_\_\_\_\_

DATE CONSIDERED \_\_\_\_\_

EXAMINER Initial if reference considered whether or not citation is in conformance with MPEP 600. 1-11-01

<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office  <b>LIST OF DOCUMENTS CITED BY APPLICANT</b>  (Use several sheets if necessary)		Attorney Docket Number 9233.14DV	Serial No. 10/808,044
		Applicants: Ekwuribe et al.	
		Filing Date: March 24, 2004	Group
	16.	U.S. Patent Application No. 10/774,903, entitled "Amphiphilic Drug-Oligomer Conjugates with Hydrolyzable Lipophile Components and Methods for Making and Using the Same" filed February 9, 2004	
	17.	U.S. Patent Application No. 10/811,760, entitled "Drug-Oligomer Conjugates" filed March 29, 2004	
	18.	U.S. Patent Application No. 10/395,548, entitled "Taxane Prodrugs" filed March 24, 2003	
	19.	U.S. Patent Application No. 09/429,798, entitled "Blood-Brain Barrier Therapeutics" filed October 29, 1999	
	20.	U.S. Patent Application No. 09/430,735, entitled "Methods of Inducing Analgesia" filed October 29, 1999	
	21.	U.S. Patent Application No. 10/716,975, entitled "Methods of Activating Receptor Using Amphiphilic Drug-Oligomer Conjugates" filed November 19, 2003	
	22.	U.S. Patent Application No. 10/716,578, entitled "Methods of Altering the Binding Affinity of a Peptide to its Receptor" filed November 11, 2003	

EXAMINER

DATE CONSIDERED

\*EXAMINER

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.